July 23, 2020

Palliare Ltd.
% Paul Dryden
Consultant
Palliare Ltd c/o ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, FL 33704

Re: K193520
Trade/Device Name: EVA15 Insufflator
Regulation Number: 21 CFR§ 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF
Dated: June 23, 2020
Received: June 25, 2020

Dear Paul Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jason R. Roberts, Ph.D.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

510(k) Summary

Submitter: Palliare Ltd.
Galway Business Park, Dangan
Galway H91 P2DK, Ireland

Official Contact: John O'Dea, Ph.D., Director
Tel: +353-91-516362
Email: jodea@palliare.com

Contact Person name: Paul Dryden
ProMedic, LLC
131 Bay Point Dr NE
St. Petersburg, FL 33704

Date Prepared: July 21, 2020

Proprietary or Trade Name: EVA15 Insufflator
Regulation number: 21 CFR 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: Class II
Product Code: HIF

Predicate Device: K172516 – SurgiQuest AirSeal iFS System

The predicate devices has no been subject to a design-related recall.

Device Description: The EVA15 insufflator is intended for use in diagnostic and/or therapeutic endoscopic and laparoscopic procedures to distend a cavity by filling it with gas and to evacuate surgical smoke. It is indicated to facilitate the use of various endoscopic and laparoscopic instruments by filling the abdominal or thoracic cavity or rectum with gas to distend it, and by evacuating surgical smoke. The EVA15 Insufflation is intended to use in hospital. It consists of the following major components: (1) a micro-processor-controlled insufflation and smoke evacuation unit and (2) a disposable tube set.

There are 3 operating modes:

- Flow Mode (1) – delivers a fixed flow, settable between 0 and 15 standard liters per minute (SLPM)
- Pressure Modes (2) –
    - Intermittent Pressure Insufflation – a pressure is targeted, but the flow delivered in targeting that pressure is capped at 12 SLPM (i.e. no more than 12 SLPM will be delivered during intermittent pressure insufflation).
    - Continuous Pressure Insufflation – a pressure is targeted, but the flow delivered in targeting that pressure is capped at 40 SLPM (i.e. no more than 40 SLPM will be delivered during continuous pressure insufflation).

The tubeset is a sterile, single-use product. The tubeset is made of PVC and polyethylene. The AVA15 Insufflator is an active medical device, nonsterile and reusable and is intended to insufflate a body cavity up to 15mmHg and with up to 40 SLPM instantaneous flow. The EVA15 is powered by AC and uses compressed 50 psi CO_2 and air gas supplies to supply the pneumatic

circuitry for insufflation and smoke evacuation, respectively.

Principle of Operation: The operating principle employs 2 methods.

A) A digital insufflation pressure regulation system using compressed CO_2 gas to deliver CO_2 into the patient cavity to be insufflated at the direction and control of the physician; and

B) The use of a venturi method to create a vacuum to evacuate any smoke created during the procedure.

Indications for Use:
The EVA15 Insufflator is intended for use in diagnostic and/or therapeutic endoscopic and laparoscopic procedures to distend the abdomen, colon or thoracic cavity with up to l5 mmHg pressure, by filling it with gas and to evacuate surgical smoke.

Comparison of Technological Characteristics of the subject and predicate devices are presented in **Table 1** below.

Table 1 – Comparison – Subject vs. Predicate

	Subject Device: EVA15 Insufflator (K193520)	**Predicate Device: SurgiQuest AirSeal iFS System (K172516)**	**Comparison**
Manufacturer	Palliare Ltd.	SurgiQuest Inc. (Acquired by ConMed Co. in 2015)	
Classification	21 C.F.R. § 884.1730 (*Laparoscopic Insufflator*), Product Code HIF	21 C.F.R. § 884.1730 (*Laparoscopic Insufflator*), Product Code HIF, GCJ	Same
Fundamental scientific technology	Digital insufflation pressure regulation system using compressed CO_2 gas. Venturi smoke evacuation.	Digital insufflation pressure regulation system using compressed CO_2 gas Smoke evacuation using custom trocar generating negative pressure	Similar
Patient connection	Standard Trocar luer connection	Customized trocar	Similar - each connects to cavity using a trocar
Indications for Use	The EVA15 Insufflator is intended for use in diagnostic and/or therapeutic endoscopic and laparoscopic procedures to distend the abdomen, colon or thoracic cavity with up to l5 mmHg pressure, by filling it with gas and to evacuate surgical smoke.	The SurgiQuest AirSeal® iFS System is intended for use in diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas, to establish and maintain a path of entry for endoscopic instruments and to evacuate surgical smoke. It is indicated to facilitate the use of various thoracoscopic and laparoscopic instruments by filling the abdominal or thoracic cavity with gas to distend it, by creating and maintaining a gas sealed obstruction-free instrument path and by evacuating surgical smoke. This instrument can also be used to insufflate the rectum and colon to facilitate endoscopic observation, diagnosis and treatment. The trocar of the AirSeal® iFS System is indicated for use with or without visualization.	Similar except the subject device does not include a trocar.

	Subject Device: EVA15 Insufflator	Predicate Device: SurgiQuest AirSeal iFS System (K172516)	Comparison
Gas Delivery Modes	Fixed Flow Intermittent Pressure (Standard) Insufflation Continuous Pressure Insufflation	Intermittent Pressure (Standard and Smoke Evac Modes) Insufflation Continuous Pressure Insufflation (Airseal Mode)	Similar Subject device also has a fixed flow mode
Smoke Evacuation	Available in all modes. Operates continuously or may be activated on/off using foot pedal.	Available in Airseal (continuous pressure) and Smoke Evacuation modes. Operates continuously.	Similar
Flow Range	0-40 SLPM	0-40 SLPM	Same
Pressure Range	7-15 mmHg	5-20 mmHg	Similar Subject device has a smaller range
Accessories	Tubeset	Tubeset, Custom Trocar	Similar
Dimensions	160x130x330mm	420x220x470mm	Similar Subject is smaller
Weight	5.5kg	26.0kg	Similar Subject is smaller
Power Source	AC 100-240V	AC 100/115/230V	Similar
Tubeset Sterilization	EtO	EtO	Same
User Interface	Membrane Panel	Touchscreen	Similar

Discussion of Differences

The differences in technological characteristics do not raise different questions of safety and effectiveness when compared to the predicate.

Summary of Non-clinical Performance Testing
The subject devices comply with voluntary standards for electrical safety, and electromagnetic compatibility. The following data were provided in support of the substantial equivalence determination:

Bench

- Static condition
  - Pressure and flow delivery accuracy; the device was demonstrated to meet predefined acceptance criteria regarding pressure and flow
- Dynamic condition
  - Simulated leak; the device was demonstrated to meet predefined acceptance criteria under simulated leak conditions
  - Smoke evacuation; the device was demonstrated to meet predefined acceptance criteria regarding smoke evacuation
- Efficiency of Smoke Evacuation Filter; the device was demonstrated to meet predefined acceptance criteria regarding the smoke evacuation filter

Software was validated per *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, issued on May 11, 2005.

Electrical / EMC

- Electrical Safety
  - IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012)
  - IEC 60601-1-8: 2012

  The device was demonstrated to meet the requirements of the standard.
- EMC
  - IEC 60601-1-2:2014

  The device was demonstrated to meet the requirements of the standard.

Sterility and Aging Effect
Sterilization of the tubeset is via EtO and was validated per ISO 11135:2014/Amd.1:2018 Annex E, Half cycle approach. In addition, testing to ISO 10993-7:2008/Amd 1:2019, ASTM D4169-16, ASTM F1886 (visual inspection), ASTM F2096 (leak detection), ASTM F88 (seal strength) and ASTM F-1980-16 (aging) supported a shelf-life of 1 year.

Substantial Equivalence Conclusion
The performance testing described above demonstrate that the subject device is as safe and effective as the predicate device and supports a determination of substantial equivalence.